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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,620	02/08/2002	Gholam-Reza Zadno-Azizi	38349-0102C	3007

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT PAPER NUMBER

3738

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/071,620

Applicant(s)

ZADNO-AZIZI ET AL.

Examiner

Urmi Chattopadhyay

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2005 and 31 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-25, 27-30 and 32-54 is/are pending in the application.
- 4a) Of the above claim(s) 16-24, 28-30 and 34-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25, 27, 32, 33 and 52-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/20/04, 12/3/04
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. The Amendment filed 1/3/05 and Response to Notice of Non-Compliant Amendment filed 3/31/05 have been entered. The changes to the drawings, specification and claims have been approved by the examiner. Claims 26 and 31 have been canceled, and new claim 54 has been added. Claims 16-25, 27-30 and 32-54 are currently pending, of which claims 16-24, 28-30 and 34-51 remain withdrawn from consideration. The claims being considered for further examination on the merits are claims 25, 27, 32, 33 and 52-54.

### ***Information Disclosure Statement***

2. The Information Disclosure Statements filed 9/20/04 and 12/3/04 have been considered. An initialed and signed copy of each PTO-1449 is enclosed herewith.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 54 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While there is support in the specification for “pulmonic placement” of the device and that a “one-way valve positioned distal to the native pulmonic valve within the pulmonary artery could be of substantial benefit”, there is no support for the pulmonic passageway specifically being a lung passageway and the resilient seal sealing with a wall of the lung passageway. The claimed limitation is not commensurate in scope with what is disclosed because the limitation is narrower, and therefore is considered new matter.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 54 is rejected under 35 U.S.C. 102(e) as being anticipated by Alferness et al. (USPN 6,293,951, as cited in applicant’s IDS).

Claim 54 includes new matter, and therefore does not receive the benefit of filing of the parent applications. The claim has an effective filing date of the filing date of the application, which is 2/8/02.

Alferness et al. discloses a method of treating a patient using a flow control valve prosthesis with all the elements of claim 54. See Figure 7 and column 2, lines 28-38 for placing in a lung passageway a flow control device. See Figure 11 for the flow control device (110) having a resilient seal (96), a frame (100), and a valve body. See column 6, lines 24-28 for

Art Unit: 3738

permitting the frame (100) to self-expand within a passageway sufficiently to anchor the device within the lung passageway, and column 5, lines 50-53 for the resilient seal (96) sealing with a wall of the lung passageway so as to prevent fluid flow between the resilient seal and the wall of the lung passageway. See Figure 11 and column 6, lines 44-45 for the valve body having a first portion (104) movable between an open configuration allowing fluid to flow through the lung passageway and a closed configuration restricting fluid flow through the lung passageway. Because the first portion is formed from slits in the circular base (94), the first portion (104) is biased into the closed configuration.

*Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 25, 27, 32, 33, 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonhardt et al. (USPN 5,957,949 as cited in applicant's IDS) in view of Andersen et al. (USPN 5,411,552 as cited in previous office action), Love (USPN 4,470,157) and Lentz (USPN 5,522,881).

Leonhardt et al. discloses a method of treating a patient using a flow control valve prosthesis with all the elements of claim 25, but is silent to placing the flow control device specifically in a pulmonic passageway of the patient. See column 1, lines 11-20 for placing in any passageway that flow control is desired a flow control device (20). See Figure 4 for the flow

Art Unit: 3738

control device having a resilient seal (24), a frame (26), and a valve body (22). See Figures 9A-9B, column 10, lines 53-58 and column 11, lines 13-15 for permitting the frame (26) to self-expand within a passageway and column 5, lines 45-49 for the resilient seal (24) sealing with a wall of the passageway so as to prevent fluid flow between the resilient seal and the wall of the passageway. See column 1, lines 11-14 for the valve body having a first portion movable between an open configuration allowing fluid to flow through the valve body and a closed configuration restricting fluid flow through the valve body. Andersen et al. teaches that it is old and well known for a flow control valve prosthesis to be used in several different passageways, including the aorta and the pulmonary artery. See column 3, lines 43-52. It would have been obvious, therefore, to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Andersen et al. to use the flow control device of Leonhardt et al., which is disclosed as being used in the aorta or any other passageway requiring flow control, in the alternative passageway of the pulmonary artery (pulmonic passageway).

Leonhardt et al. is also silent to the first portion being biased into the closed configuration. Love teaches applying stitches or clips (20) to bias close the cusps of a prosthetic heart valve in order to close the valve once the pressure differential, which caused the edges of the cusps to separate for blood to flow through, terminates. Any back pressure will force the edges of the cusps to seal tighter against the edges of adjacent cusps. See Figure 3, column 3, lines 39-49 and column 5, lines 40-44. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Love to modify the valve body of Leonhardt et al. and Andersen et al. by biasing the cusps of a mechanical valve into the closed configuration in order to close the valve once the pressure differential terminates. Any back

Art Unit: 3738

pressure will force the edges of the cusps to seal tighter against the edges of adjacent cusps. The examiner contends that this will better guard against valvular regurgitation at any point during pumping of the heart.

Leonhardt et al. is also silent to the self-expansion of the frame within the passageway being sufficient to anchor the device therein. Lentz teaches a stent-graft (10) wherein the stent (28) is designed to radially self-expand with a force sufficient to anchor the stent-graft (10) within a lumen (32) of a vessel (34) to form a liquid seal therein without placing disruptive force or undue pressure on the intraluminal walls. See Figure 7 and column 5, lines 8-9 and 17-21. Because the super elasticity of the self-expanding frame (26) of Leonhardt allows it to “conform to and seal against the dramatically different structures occurring within vessel walls and valve locations” (column 4, lines 60-65), it would have been obvious to one of ordinary skill in the art that the self-expansion force of the frame (26) that is forming a seal with the vessel is sufficient to anchor the device within the vessel. The expansion balloon (154) will then be used to simply maintain the anchored position of the device during the remainder of the deployment procedure when displacement forces acting on the device will be greater than the forces acting on the device during use.

Claim 27, see column 4, lines 26-28 for the frame (26) being comprised of a material having spring resilience. See Figures 9A-9D and columns 10-11, lines 53-21 for releasing the preconstraint (106) to allow the frame (26) to expand to an expanded state so as to engage the passageway.

Claim 32, see column 11, lines 3-22 for resilient seal sealing against passageway during placement.

Art Unit: 3738

Claim 33, see column 1, lines 11-13 for one-way valve providing one direction fluid flow.

Claim 52, see column 6, lines 25-26 for the frame being coupled to the valve body.

With respect to claim 53, see Figures 9A-9D. The definition of “distort”, according to [www.webster.com](http://www.webster.com) is “to twist out of a natural, normal, or original shape or condition”. The definition of “distort” according to Webster’s II New Riverside University Dictionary is “to twist out of proper shape or relation”. The term “distort” is given its plain meaning (dictionary definitions) because the specification does not clearly set forth a definition explicitly and with reasonable clarity, deliberateness and precision of the term. Because the valve body is reverting back to its natural and normal shape to provide as a patent one-way valve when the frame expands, the valve body does not “distort” (as defined) when the frame expands.

#### ***Response to Arguments***

8. In the Office Action mailed 6/29/04, claim 33 was rejected under 35 USC 112, second paragraph. As pointed out by the applicant, the examiner meant to reject claim 32, and not claim 33. In light of applicant’s arguments, the rejection has been withdrawn.

9. Applicant's arguments with respect to claims 25, 27, 32, 33 and 52-54 have been considered but are moot in view of the new ground(s) of rejection.



*Conclusion*

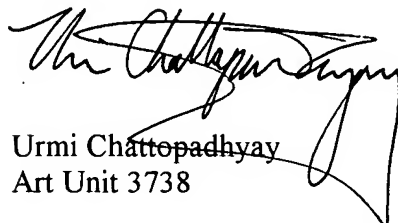
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

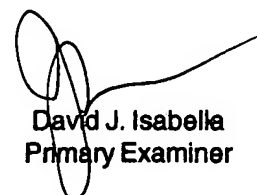
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached on Tuesday-Thursday 10:00am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Urmi Chattopadhyay  
Art Unit 3738

  
David J. Isabella  
Primary Examiner